

APR 25 1997



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#18

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P.O. Box 2500  
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In Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,379,785

### NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,379,785, which claims the human drug product AMARYL® (glimepiride) and a method of use of the human drug product AMARYL® (glimepiride), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,571 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of May 29, 1996 (61 Fed. Reg. 26,913). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,225) + 458 \\ &= 1,571 \text{ days (4.3 years)}\end{aligned}$$

Since the regulatory review period began July 28, 1988, after the patent issue date (April 12, 1983), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the five year limitation of 35 U.S.C. § 156(g)(6)(B) nor the 14 year limitation of 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 1,571 days.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	4,379,785
Granted	:	April 12, 1983
Original Expiration Date	:	December 17, 2000

Applicant	:	Rudi Weyer et al.
Owner of Record	:	Hoechst Aktiengesellschaft
Title	:	Heterocyclic Substituted Sulfonyl Ureas, and Their Use
Classification	:	514/183
Product Trade Name	:	AMARYL® (glimepiride)
Term Extended	:	1,571 days
Expiration Date of Extension	:	April 6, 2005


Any correspondence from applicant with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents  
Box Patent Ext.  
Washington, D.C. 20231

By FAX: (703) 308-6916  
Attn: Special Program Law Office

By hand: One Crystal Park, Suite 520  
2011 Crystal Drive  
Arlington, VA

Telephone inquiries related to this determination should be directed to Karin Tyson at (703) 306-3159.

  
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Hiram H. Bernstein  
Senior Legal Advisor  
Special Program Law Office  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fishers Lane, Room 15-22  
Rockville, MD 20857

RE: AMARYL® (glimepiride)  
FDA Docket No.: 96E-0044